

### **REMARKS/ARGUMENTS**

In response to the Final Office Action mailed May 14, 2007, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claims 1 and 20 are proposed to be amended, no claims have been added, and no claims have been cancelled so that Claims 1- 40 are currently pending. No new matter has been introduced.

Claims 1 and 20 were rejected under 35 U.S.C. § 112, first paragraph. Applicants have amended the claims in accordance with the wording of the specification.

Claims 1-10, and 20-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,472,702 to Muth et al (Muth) in view of U.S. Patent No. 5,749,203 to McGowan, Jr. (McGowan), and U.S. Patent No. 5,464,580 to Popescu et al. (Popescu et al. (Popescu) and further in view of EP 0 568 310 to Mitchell (Mitchell) as evidenced by Sigma-Aldrich. This rejection is respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” In *re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).”

Muth discloses the sterilization, utilizing ethylene oxide, of human growth factor, a human growth factor containing composition and/or a medical or surgical device such as a wound dressing or suture filled with human growth factor containing composition. Muth specifically details the sterilization parameters. For example, Muth discloses a preferable temperature range of about 85°C. to about 95°C, a preferable time range of about 6 hours to about 10 hours and a relative humidity range of about 40 percent to about 70 percent. For the sake of this response we shall assume that the temperature range is 85°F to 95°F rather than centigrade as specified in the patent and text above.

McGowan discloses a method of packaging a medical article. More particularly, McGowan discloses a sterilant gas sterilization process for sterilizing surgical articles formed from nonwoven fabrics, such as surgical gowns and drapes formed from polymeric materials. The articles to be sterilized are first conveyed to form-fill and seal machines (EFS) and then the sterilizing agent is introduced. One sterilizing agent disclosed is ethylene oxide. The sterilizing agent is mixed with a carrier gas such as nitrogen. This mixture reduces the possibility of ethylene oxide ignition. The gas mixture may be heated to a working range of 70°F to about 170°F in up to eighteen hours. The sterilization plant may also comprise an ethylene oxide eliminator system. In addition, McGowen discloses the use of washes and vacuums.

Mitchell discloses a pharmaceutical composition for treating hyperproliferative vascular disease. Mitchell discloses that rapamycin and heparin may be delivered in any number of suitable ways.

Popescu discloses a sterilization process for moisture sensitive products. The process includes nitrogen washes.

As set forth above, the prior art references must teach or suggest all the claim limitations. It is respectfully submitted that the prior art references, whether taken alone or in combination, fail to teach or disclose all of the claimed limitations. In Claims 1 and 20, the step of removing the sterilization agent from the sterilization chamber through a plurality of separate vacuum and nitrogen washes over a third predetermined period with the temperature in the range from about thirty degrees C to about forty degrees C for the specific period of six to seventeen hours in combination with the other steps is simply not suggested. The closest reference in McGowan which teaches, in detail, the mixing of the sterilizing agent with a carrier gas such as nitrogen, is not even remotely the same as what is claimed in amended Claim 1 and Claim 20. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

In a Memorandum dated May 3, 2007 from Margaret A. Focariono, Deputy Commissioner for Patent Operations, it is stated that “in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.”

It is respectfully submitted, that it is known to remove the sterilizing agent but that the present invention does this through a series of vacuums and washes over six to seventeen hours.

Claims 11-13 and 32-24 were rejected as being unpatentable over Muth in view of McGowan, Popescu and Mitchell as further evidenced by Sigma-Aldrich and further in view of U.S. Patent No. 6,025,414 to Rich and U.S. Patent No. 3,675,647 to Pharriss et al. (Pharriss). This rejection is respectfully traversed.

Rich and Pharriss, whether taken alone or in combination, fail to disclose or even remotely suggest the elements of claims 1 and 20 from which the rejected claims depend, thus failing to cure the deficiency in the rejection of claims 1 and 20 as set forth above. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 14-19 and 35-40 were rejected as being unpatentable over Muth in view of McGowan, Popescu and Mitchell as further evidenced by Sigma-Aldrich and further in view of WO 00/38754 to Gingras. This rejection is respectfully traversed.

Gingras fails to disclose or even remotely suggest the elements of claims 1 and 20 from which the rejected claims depend, thus failing to cure the deficiency in the rejection of claims 1 and 20 as set forth above. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview if the Examiner believes it would be helpful in disposing of the present case.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

/Carl J. Evens/

By: \_\_\_\_\_  
Carl J. Evens  
Reg. No. 33,874

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-2518  
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